

SAT Report

PMN Number: P-13-0687

SAT Date: 7/16/2013

Print Date: 11/26/2014

Related cases:

Concern levels:

Type of Concern:	<u>Health</u>	<u>Eco</u>	<u>Comments</u>
Level of Concern:	2	2	

<u>Persistence</u>	<u>Bioaccum</u>	<u>Toxicity</u>	<u>Comments</u>
2	1	2	
		Awaiting	
		Human Health	
		Entry	
		Awaiting	
		Human Health	
		Entry	
		Awaiting	
		Human Health	
		Entry	

Exposure Based Review:

Health: No

Ecotox: Yes

Routes of exposure:

Health: Drinking Water Inhalation

Ecotox: All releases to water

Fate: ;

Keywords:

Keywords:

Summary of Assessment:

Fate:

Fate Summary: P-13-0687

FATE: Estimations for low weight [REDACTED], covalent ion pair

MW 451 [REDACTED]

Solid with MP = 90 C (E)

log Kow = -7.57 (E)
 S > 10 g/L at 25 C (E)
 VP < 1.0E-6 torr at 25 C (E)
 BP > 400 C (E)
 H < 1.00E-8 (E)
 log Koc = 2.65 (E)
 log Fish BCF = 0.50 (E)
 log Fish BAF = -0.05 (E)
 POTW removal (%) = 050 via biodeg
 Time for complete ultimate aerobic biodeg = mo
 Sorption to soils/sediments = low
 PBT Potential: P2B1
 *CEB FATE: Migration to ground water = rapid

Health:

Health Summary: Absorption is nil through the skin, moderate through the GI tract, and good through the lungs based on physical/chemical properties. There is concern for developmental toxicity due to [REDACTED] and based on information submitted in [REDACTED] for the free acid that showed skeletal effects in pups at 1 g/kg and resorptions and decreased fetal weights at 2000 mg/kg along with maternal toxicity at both dose levels. There is also concern for effects on the bone and bone cancer based the [REDACTED] The Q1* value for [REDACTED] is based on osteogenic sarcomas seen after oral administration in male rats.

Ecotox:

Test Organism	Test Type	Test End Point	Predicted	Measured	Comments
fish	96-h	LC50	>100		
daphnid	48-h	LC50	>100		
green algal	96-h	EC50	20		
fish	—	chronic value	>10		
daphnid	—	chronic value	>10		
algal	—	chronic value	7.4		
Sewage Sludge	3-h	EC50	—		
Sewage Sludge	—	Chronic Value	—		

Ecotox Values Comments:

Factors	Values	Comments
Assessment Factor	10	
Concentration of Concern (ppb)	740	

SARs		
SAR Class		
Ecotox Category		

Ecotox Factors Comments:

SAT Chair: L Keifer 564-8916

Focus Report
New Chemicals Program
PMN Number: P-13-0687

Focus Date: 07/24/2013 11:00:00 PM Report Status: Completed
Consolidated Set:
Focus Chair: Loraine Passe Contractor: Jean Quenneville

I. Notice Information

Submitter: Compass Chemical International LLC
Chemical Name:

CAS Number:

Use:

Other Uses: None found.

PV-Max:

Manufacture:

X

Import:

II. SAT Results

(1) Health Rating: 2

Eco Rating: 2

Comments: ;

Occupational: 1C

Non-Occupational: 3

Environmental: 3

(1) PBT: 2 1

2

Comments:

III. OTHER FACTORS

Categories:

Health Chemical Category:

Ecotox Category:

Related Cases/Regulatory History:

Health related Cases:

Ecotox Related Cases: Similar Case . Analogs:

Regulatory History:

-REG NON SE SNUR
-Excluded from reporting
-Excluded from reporting
-Final conditional grant
-WITHDRAWN - OTHER
-OR MID-COURSE DISP DROP
-WITHDRAWN - OTHER
-SR MID-COURSE DISP DROP/FR

MSDS/Label Information:

MSDS: Yes

Label: No

General Equipment: Safety glasses with side shields or goggles, chemical resistant gloves, long sleeves, safety shower and eyewash station.

Respirator: Where overexposure by inhalation may occur and engineering, work practice or other means of exposure reduction are not adequate, approved respirators may be necessary.

Health Effects: Eyes: Irritating, but does not injure eye tissue. Skin: Prolonged or repeated contact may irritate. Ingestion: Swallowing this material may be harmful. Inhalation: Vapors and/or aerosols may be irritating to eyes and respiratory tract.

TLV/PEL (PMN or raw material): - None established.

Exposure Based Information:

Exposure Based Review: Y

Exposure Based Review (Health): N

Exposure Based Review (Eco): Y

Exposure Based (Occupational): No

Exposure Based Review: N

Exposure Based (Environmental): Y

(Non Occupational):

Exposure Parameter	Exposure-Based	Persistent/Bioaccum	Exposure Value
Surface DW:		Yes	
Fish Ingestion:			
Ground DW:	Yes		
Inhalation:	Yes		
Water Releases:	Yes		
Total Releases:	Yes		
Consumer Exposure:	Yes		

IV. Summary of SAT Assessment

Fate:

Fate Summary:

P-13-0687

FATE: Estimations for

Solid with MP = 90 C (E)

log Kow = -7.57 (E)

S > 10 g/L at 25 C (E)

VP < 1.0E-6 torr at 25 C (E)

BP > 400 C (E)

H < 1.00E-8 (E)

log Koc = 2.65 (E)

log Fish BCF = 0.50 (E)

log Fish BAF = -0.05 (E)

POTW removal (%) = 0-50 via biodeg

Time for complete ultimate aerobic biodeg = mo

Sorption to soils/sediments = low

PBT Potential: P2B1

*CEB FATE: Migration to ground water = rapid

Health:

Health Summary:

Absorption is nil through the skin, moderate through the GI tract, and good through the lungs based on physical/chemical properties. There is concern for developmental toxicity due to and based on information submitted in for the that showed skeletal effects in pups at 1 g/kg and resorptions and decreased fetal weights at 2000 mg/kg along with maternal toxicity at both dose levels. There is also concern for effects on the bone and bone cancer based the . The Q1* value for is based on osteogenic sarcomas seen after oral administration in male rats.

Ecotox:

Ecotox Values:

Fish 96-h LC50: >100(P)

Daphnid 48-h LC50: >100(P)

Green algal 96-h EC50: 20(P)

Fish Chronic Value: >10(P)

Daphnid ChV: >10(P)

Algal ChV: 7.4(P)

Ecotox values comments:

Predictions are based on SARs for

solid with mpunknown (P); S > 500 g/L at 20 C (M); pH7; effective concentrations based on 100% active ingredients and nominal concentrations; hardness < 150.0 mg/L as CaCO3; and TOC <2.0 mg/L;

Ecotox Factors:

Assessment Factor: 10

Concern Concentration: 740

V. Summary of Exposures/Releases

Engineering Summary: P-13-0687

Exposures/Releases	Release	Release	Release
Scenario			
Sites			
Media			
Descriptor A	Output 2	Conservative	Conservative
Quantity A (kg/site/day)			
Frequency A (day/year)			
Descriptor B			
Quantity B (kg/site/day)			
Frequency B (day/year)			
From			
Workers			
Exposure Type			

Engineering Summary: Exposures/Releases	Release	Release	Release
Scenario			
Sites			
Media			
Descriptor A	High End	High End	Output 2
Quantity A (kg/site/day)			
Frequency A (day/year)			
Descriptor B			
Quantity B (kg/site/day)			
Frequency B (day/year)			
From			
Workers			
Exposure Type			

V. Summary of Exposures/Releases

Engineering Summary: P-13-0687

Exposures/Releases	Release	Release	Release
Scenario			
Sites			
Media			
Descriptor A	Output 2	Output 2	High End
Quantity A (kg/site/day)			
Frequency A (day/year)			
Descriptor B			
Quantity B (kg/site/day)			
Frequency B (day/year)			
From			
Workers			
Exposure Type			

Engineering Summary: Exposures/Releases	Release	Release	Release
Scenario			
Sites			
Media			
Descriptor A	Output 2	High End	Output 2
Quantity A (kg/site/day)			
Frequency A (day/year)			
Descriptor B			
Quantity B (kg/site/day)			
Frequency B (day/year)			
From			
Workers			
Exposure Type			

V. Summary of Exposures/Releases

Engineering Summary: P-13-0687

Exposures/Releases	Exposure	Exposure	Exposure
Scenario			
Sites			
Media			
Descriptor A	High End	High End	High End
Quantity A (kg/site/day)			
Frequency A (day/year)			
Descriptor B			
Quantity B (kg/site/day)			
Frequency B (day/year)			
From			
Workers			
Exposure Type			

Engineering Summary: Exposures/Releases	Exposure	Exposure	
Scenario			
Sites			
Media			
Descriptor A	High End	High End	
Quantity A (kg/site/day)			
Frequency A (day/year)			
Descriptor B			
Quantity B (kg/site/day)			
Frequency B (day/year)			
From			
Workers			
Exposure Type			

VI. Focus Decision and Rationale

Regulatory Actions

Regulatory Decision: PMN Ban Pending Upfront Testing

Decision Date: 07/24/2013

Type of Decision:

Rationale:

P-13-0687 will be regulated under the TSCA 5(e) category [REDACTED] Ban Pending-Up Front Testing under the risk based authority for ecotoxicity hazard concerns and exposure-based human health and ecotoxicity concerns. Human health hazard concerns were moderate for inhalation exposures. Potential risks to workers were mitigated by negligible vapor exposures. Ecotoxicity hazard concerns were moderate based on SAR predictions for [REDACTED]. Chronic risks to the environment were high due to releases to water where the chronic COC of 740 ppb was exceeded 80 [REDACTED] days ([REDACTED]) during manufacturing operations, 177 [REDACTED] days [REDACTED] during processing operations, 219 [REDACTED] days [REDACTED] during use 1 operations, 38 [REDACTED] days [REDACTED] during use 2 operations, and 164 [REDACTED] days [REDACTED] during use 3 operations. Acute risks to the environment were high due to releases to water where the SWCs of [REDACTED] during manufacturing, [REDACTED] during processing operations, [REDACTED] during use operations, [REDACTED] during use 2 operations and [REDACTED] during use 3 operations exceeded the acute COC of 5,000 ppb. The required ecotoxicity testing will be the acute base set: Freshwater daphnids (OPPTS Test Guidelines 850.1010), Fish acute toxicity test, freshwater (OPPTS Test Guidelines 850.1075), and the Algal toxicity test (OCSPP Test Guidelines 850.4500). The required fate testing will be the Porous pot test (OPPTS 835.3220) or the Zahn-Wellens/EMPA test (OPPTS 835.3200). The required human health testing will be the Combined repeated dose toxicity with the reproduction/development toxicity screening test (OECD 422). No CEB exposure-based criteria were met. The following EAB exposure-based criteria were met: [REDACTED]

COC: Chronic – 740 ppb, Acute – 5,000 ppb

Summary of Exposures and Releases

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] over 350 days/yr

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

P2 Rec Comments:
Testing:
Final Recommended:
Health:
Eco:
Fate:
Other:

PMN Summary

Case Number: P-13-0687 **Day in Process:** 91 **Total Days:** 364
Consolidated Cases: No **PMN Summary Only?** ☐ Yes ☒ No
PMN Day 1: 07/08/2013 **Original PMN Day 90:** 10/05/2013
Total Days Suspended: 268 **PMN Day 90 (30,45,60):** 06/30/2014

Phase	Status	Decision
Post Focus	Archive	PMN Ban Pending Upfront Testing Decision Date: 07/25/2013 Decision Type: Decision History: CRSS Decision of Move Forward made on 07/15/2013 Focus Decision of PMN Delay made on 07/18/2013 Focus Decision of PMN Ban Pending Upfront Testing made on 07/25/2013

Date	Final Disposition
Disposition History:	Withdrawn on 06/26/2014
CRSS Descriptors:	YX-Exposure-Based 5(e)
Additional Descriptor:	
Withdrawn Date:	

CRSS Date:	07/14/2013	Document Type: Premanufacture Notice (PMN) Case Number: P-13-0687 Day(1): 07-08-2013 Document Processing Comments: SRN: XXX3130708252898752 Submission File Name: formdata.pdf Attachments(s) <ul style="list-style-type: none"> ● Name: Operation description.pdf ● Name: Ammonium salt of MQ-2350 -MSDS.pdf ● Name: Flow diagram.pdf ● Name: CAS Registry Lookup Results3.pdf ● Name: AEEA-Phosphonate (MQ-2350) Process.pdf ● Name: MQ-2350 Properties.pdf
SAT Date:	07/16/2013	
Focus Date:	07/24/2013	

Chemist:	Schechter, K.	Engineer:	Choudhary
SAT Chair:	L Keifer 564-8916	Exposure Specialist:	Cinalli/SD
Focus Chair:	Loraine Passe	Contractor Support:	<input checked="" type="radio"/> Yes <input type="radio"/> No

PMN Attributes

Chemical	
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Name:			
Submitter:	Compass Chemical International LLC	Trade Name:	Mayoquest 2350
Contact:	Stephen Redding	Contact Telephone Number:	(678) 904-4071 sredding@compasschemical.com
Manufacture:	X	Import:	
Polymer:	<input type="radio"/> Yes <input checked="" type="radio"/> No	Grouping for CRSS:	
		Grouping for Focus:	
Production Volume:		Binding Option:	No
ES Order No.:		CAS Number:	
Uses:			

Ratings and Concern Levels:

	Health Ratings	Eco Ratings	Comments
(1)	2	2	;

Occupational Exposure:	1C
Non-Occupational Exposure:	3
Environmental Exposure:	3
Engineering Drop Criteria/Exposure Drop:	/

Persistence	Bioaccumulation	Toxicity	PBT Comments
(1) 2	(1) 1	(1) 2	(1)

Exposure Based Information

Exposure Based Review (Chemistry): ☒ Yes ☐ No Exposure Based Review (Health): ☐ Yes ☒ No

Exposure Based Review (Ecotox): ☒ Yes ☐ No Exposure Based Review (Occupational): 1

Exposure Based Review (Non-Occupational): ☒ Yes ☐ No Exposure Based Review (Environmental): ☒ Yes ☐ No

Criteria		Criteria	
1. Number of Workers Exposed > 1000?	0	1. Exposure-Based Fate--Surface Drinking Water?	<input type="radio"/> Yes <input checked="" type="radio"/> No
2. > 100 Workers With > 10 mg/Day Inhalation Exposure	0	2. Fish Ingestion:	<input type="radio"/> Yes <input checked="" type="radio"/> No
3a. > 100 Workers With 1-10 mg/Day Inhalation Exposure >100 Days/Yr	0	3. Exposure-Based Fate--Ground Drinking Water?	<input checked="" type="radio"/> Yes <input type="radio"/> No
3b. > 250 Workers With Routine Dermal Contact > 100 Days/Yr	0	4. Exposure-Based Fate--Inhalation?	<input checked="" type="radio"/> Yes <input type="radio"/> No
		5. Exposure-Based Fate--Water Releases?	<input checked="" type="radio"/> Yes <input type="radio"/> No
		6. Total Releases:	<input checked="" type="radio"/> Yes <input type="radio"/> No
		7. Consumer Exposure:	<input type="radio"/> Yes <input checked="" type="radio"/> No

Post Focus Agenda Information

Meeting	Meeting Date	Time	Location	Issue	Proposed Decision
CCD Dispo:			5140		
Division Director's:			4140		

Program Manager/Technical Integrator

No.	Assignment	Branch	Resource	Phone	Date Assigned
01.	Program Manager	CCD/NCNMB	Zofia Kosim	(202) 564-8733	08/01/2013

Workgroup Assignments

No.	Assignment	Branch	Resource	Phone	Date Assigned

SNUR History:

Federal Register Number ; Federal Registry Date ; Reason ; Federal Registry Citation

SNUR Citations:

Sanitization Due Date: ; SNUR notification to reviewers: ; Generic name: ☐ Yes ☐ No

Batch identifier:

CEB Rep: Eric Jackson	EAB Rep:	ICB Rep: Jasbir Sarna	RAD Rep:
Done: <input type="radio"/> Yes <input type="radio"/> No	Done: <input type="radio"/> Yes <input type="radio"/> No	Done: <input type="radio"/> Yes <input type="radio"/> No	Done: <input type="radio"/> Yes <input type="radio"/> No

Notice of Commencement:

Has the case been NOC'd? ☐ Yes ☐ No

Status History:

7/10/2013 3:27:35 PM -- Phase Initial Review -- kathryn schechter
7/10/2013 3:27:35 PM -- Status Pending CRSS -- kathryn schechter
7/11/2013 3:33:48 PM -- Status changed from Pending CRSS to Scheduled for CRSS -- kathryn schechter
7/15/2013 10:12:10 AM -- Status changed from Pending CRSS to Pending Focus -- Paul Bickart
7/15/2013 10:12:10 AM -- Decision changed from to FWD-Move Forward -- Paul Bickart
7/16/2013 1:31:53 PM -- Status changed from Pending Focus to Scheduled for Focus -- Eric Jackson

7/16/2013 1:38:43 PM -- Status changed from Pending Focus to Scheduled for Focus -- Eric Jackson

7/18/2013 2:03:21 PM -- Status changed from Pending Focus to Scheduled for Focus -- Eric Jackson

7/18/2013 2:03:21 PM -- Decision changed from FWD-Move Forward to PMN Delay -- Eric Jackson

7/25/2013 1:28:18 PM -- Phase changed from Initial Review to Post Focus -- Jean Quenneville

7/25/2013 1:28:18 PM -- Status changed from Scheduled for Focus to Ban Pending Testing -- Jean Quenneville

7/25/2013 1:28:18 PM -- Decision changed from PMN Delay to PMN Ban Pending Upfront Testing -- Jean Quenneville

9/24/2013 9:54:04 AM -- Case suspended for 61 day(s) on 9/24/2013 9:54:04 AM -- Ken Moss

10/22/2013 6:45:53 AM -- Case suspended for 16 day(s) on 10/22/2013 6:45:53 AM -- kathryn schechter

3/26/2014 3:49:36 PM -- Case suspended for 161 day(s) on 12/21/2013 -- Greg Schweer

6/6/2014 7:51:26 AM -- Case suspended for 30 day(s) on 5/31/2014 -- Greg Schweer

6/30/2014 8:23:54 AM -- withdrawn on 06/26/14 -- Zofia Kosim

New Status History Comments :

Reactivated By: Leonard Keifer -- 11/13/2014 9:09:10 AM

General Comments:

10/22/2013 6:45:53 AM -- The review period for this case was extended for 16 days due to the government furlough between October 1st 2013 and October 16th 2013. -- kathryn schechter

PMN Summary Comments :

Last Updated by Leonard Keifer on 11/18/2014 at 06:41:30 AM

Document Created by kathryn schechter on 07/10/2013